

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES***

Applicant: Ole SIBBESEN *et al.*

**Filed via EFS Web  
May 27, 2009**

Title: BACTERIAL XYLANASES

Appl. No.: 10/626,583

Filing Date: 7/25/2003

Examiner: Ganapathiram RAGHU

Art Unit: 1652

Confirmation 9539  
Number:

**AMENDED BRIEF ON APPEAL**

Mail Stop **Appeal Brief - Patents**  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Amended Appeal Brief is responsive to the Notice of Non-compliant Appeal Brief mailed **April 27, 2009**.

Applicant has previously paid the 37 C.F.R. § 41.20(b)(2) appeal fee. If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 19-0741.

<b>IN THE UNITED STATES PATENT AND TRADEMARK OFFICE .....</b>	<b>1</b>
<b>BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES.....</b>	<b>1</b>
<b>AMENDED BRIEF ON APPEAL.....</b>	<b>1</b>
<b>I.    REAL PARTY IN INTEREST .....</b>	<b>4</b>
<b>II.   RELATED APPEALS AND INTERFERENCES .....</b>	<b>4</b>
<b>III.  STATUS OF CLAIMS .....</b>	<b>4</b>
<b>IV.  STATUS OF AMENDMENTS .....</b>	<b>4</b>
<b>V.    SUMMARY OF CLAIMED SUBJECT MATTER.....</b>	<b>4</b>
<b>VI.  GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL .....</b>	<b>6</b>
<b>VII. ARGUMENT .....</b>	<b>6</b>
<b>1.    Claims 56-66, 69 and 70 are not obvious over Haarasilta or Poutanen in view of Paice or Wolf and Campbell.....</b>	<b>6</b>
<b>A.    The Examiner has failed to make a <i>prima facie</i> showing of obviousness under the rationale of <i>KSR</i>.....</b>	<b>7</b>
<b>(i).    The present invention is not a combination of prior art elements according to known methods which yield predictable results.....</b>	<b>9</b>
<b>(ii).   Claimed invention is not "obvious to try." .....</b>	<b>12</b>
<b>(iii).  No motivation to select the bacterial xylanase produced by the polynucleotide of SEQ ID NO:6 without the use of impermissible hindsight.....</b>	<b>13</b>
<b>B.    Appellants' Claimed Invention Demonstrates Unexpected Results. ....</b>	<b>14</b>
<b>C.    The Cited Art Teaches Away from the Claimed Invention. ....</b>	<b>16</b>
<b>2.    Claim 67 is not obvious over Haarasilta or Poutanen, Paice or Wolf and Campbell and further in view of Autio.....</b>	<b>18</b>
<b>3.    Conclusion .....</b>	<b>19</b>

<b>VIII. CLAIMS APPENDIX .....</b>	<b>21</b>
<b>IX. EVIDENCE APPENDIX.....</b>	<b>23</b>
<b>X. RELATED PROCEEDINGS APPENDIX .....</b>	<b>23</b>

**I. REAL PARTY IN INTEREST**

The real party in interest is Danisco A/S as reflected on an assignment recorded on October 1, 2001 at Reel 012213, Frame 0695 in parent U.S. Application No. 09/869,155. The present application is a continuation application of U.S. Application No. 09/869,155.

**II. RELATED APPEALS AND INTERFERENCES**

No other prior or pending Appeals, interferences or judicial proceedings are known to Appellants or the Appellants' legal representatives which may be related to, directly affect or be directly affected by, or have a bearing on a decision by the Board of Patent Appeals and Interferences ("the Board") in the present Appeal.

**III. STATUS OF CLAIMS**

Claims 56-67 and 69-70 are pending in the present application.

Claims 1-9, 11, 12, 14-43, 48-55 and 68 have been cancelled.

Claims 10, 13 and 44-47 are withdrawn.

Claims 56-67 and 69-70 are rejected.

Claims 56-67 and 69-70 are appealed.

**IV. STATUS OF AMENDMENTS**

No amendments to the claims have been filed subsequent to the Final Office Action dated July 31, 2008.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

Claims 56 and 60 are the sole independent claims on appeal. Claim 56 is directed to a bakery product or dough for making a bakery product, suitable for use in a foodstuff, comprising

a polypeptide which is expressed from the nucleotide sequence of SEQ ID NO:6. The polypeptide encoded by SEQ ID NO:6 is a bacterial xylanase isolated from *Bacillus subtilis*. Support for claim 56 can be found in the specification at ¶¶ [0131], [0134], [0146]-[0152], and the sequence listing, of U.S. Patent Application Publication No. 2004/0234998, which corresponds to the captioned application.

Claim 60 is directed to a dough for making a bakery product prepared by incorporating the bacterial xylanase expressed from the nucleotide sequence of SEQ ID NO:6, in which the resultant dough is less sticky than an otherwise identical dough prepared by incorporating a fungal xylanase instead of a bacterial xylanase. Support for claim 60 can be found in originally filed claims 44 and 48, as well as the specification at ¶¶ [0131], [0134], [0146]-[0152], and the sequence listing, of U.S. Patent Application Publication No. 2004/0234998

Claims 57-59 all depend directly or indirectly from claim 56 and recite further features of the polypeptide expressed from the nucleotide sequence of SEQ ID NO:6 such as the polypeptide does not contain a leader sequence or has the amino acid sequence of SEQ ID NO:5 or amino acids 29-213 of SEQ ID NO:5. Support for claim 57-59 can be found in the originally filed claims and ¶¶ [0172]-[0174] of U.S. Patent Application Publication No. 2004/0234998.

Claims 61-67 and 69-70 all depend directly or indirectly from claim 60 and recite further features of the polypeptide expressed from the nucleotide sequence of SEQ ID NO:6 (*i.e.*, the polypeptide does not contain a leader sequence or has the amino acid sequence of SEQ ID NO:5 or amino acids 29-213 of SEQ ID NO:5); or further features of the dough itself (*i.e.*, comprising wheat flour and water or yeast) or further features of the bacterial xylanase, *e.g.*, that it is free of detrimental levels of glucanase enzymes or from a *Bacillus subtilis* strain, or are directed to the bakery product prepared by baking the dough of claims 60 or 69, respectively. Support for claims 61-67 and 69-70 can be found in the originally filed claims and ¶¶ [0172]-[0174] of U.S. Patent Application Publication No. 2004/0234998.

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The issues on appeal are:

(1) whether claims 56-66, 69 and 70 are obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 5,176,927 to Haarasilta *et al.* ("Haarasilta") or Poutanen, K., *Trends in Food Science and Techol.* 8:300-306 (1997) ("Poutanen") in view of Paice *et al.*, *Arch. Microbiol.* 144:201-206 (1986) and Accession No. P184229, UnitProt Database 1990 ("Paice") or Wolf *et al.*, Accession No. I40569, PIR Database, 1996 and *Microbiology* 141:281-290 (1995) ("Wolf") and U.S. Patent No. 5,405,769 to Campbell *et al.* ("Campbell") and

(2) whether claim 67 is obvious over Haarasilta or Poutanen, Paice or Wolf and Campbell and further in view of Autio *et al.*, Academic Press, 18-27 (1996) ("Autio").

## **VII. ARGUMENT**

### **1. Claims 56-66, 69 and 70 are not obvious over Haarasilta or Poutanen in view of Paice or Wolf and Campbell.**

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 745 F.2d 1468, 1471-73 (Fed. Cir. 1984). As set forth in *Graham v. John Deere Co. of Kansas City*, "[u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is to be determined." 383 U.S. 1, 17 (1966). This has been the standard for 40 years, and remains the law today. *See KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007). If, after these criteria are considered, the evidence indicates that the claimed invention is obvious over the prior art, it may be said that a *prima facie* case of obviousness has been established.

In addition, the Examiner must show reasons, explicit or otherwise, that would compel one of ordinary skill in the art to combine the references to make and use the claimed invention. To determine whether there is "an apparent reason to combine" the known elements in the way an application claims,

It will be necessary...to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art.... To facilitate review, this analysis should be made explicit.

*Id.* at 14; *See also* Memorandum from the United States Patent and Trademark Office, "Supreme Court decision on *KSR Int'l Co. v. Teleflex, Inc.*," (May 3, 2007) ("The Court did not totally reject the use of 'teaching, suggestion, motivation' as a factor in the obviousness analysis.... [I]n formulating a rejection...based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed."). Moreover, reliance upon hindsight reasoning, based upon the Appellants' disclosure, in combining the cited references in support of the rejection under 35 U.S.C. § 103(a) is improper. *See KSR* at 17 ("A factfinder should be aware...of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."); *see also* MPEP § 2142.

**A. The Examiner has failed to make a *prima facie* showing of obviousness under the rationale of *KSR*.**

The Examiner alleges that the cited references render claims 56-67, 69 and 70 *prima facie* obvious to one of ordinary skill in the art when one applies the Teaching, Suggestion and Motivation test under the following rationale for arriving at a "conclusion of obviousness as suggested by the KSR ruling":

(1) Combining prior art elements according to known method to yield predictable results.

(2) Simple substitution of one known element for another to obtain predictable results.

(3) "Obvious to try" – choosing from a finite number of identified, predictable solution [*sic*], with a reasonable expectation of success.

Advisory Action Dated October 20, 2008 ("Advisory Action") at 11-12 and Final Office Action dated July 31, 2008 ("Final Office Action") at 13.

Additionally, the Examiner alleges that his argument is based on "Graham factual enquiries [*sic*]":

(1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem; the need here is use of novel xylanases with desirable properties for use in the a [*sic*] bakery product or dough and to identify xylanases to achieve reactions that yield the optimal alteration in the molecular properties, microstructure, functional properties and product quality.

(2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem; Knowledge of use of xylanases in the baking industry is well known in the art.

(3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and therefore there is clear motivation for commercial exploitation;...Paice et al., Wolf et al., Campbell et al., and Haarasilta et al., teach the structural and functional elements of the instant invention i.e. an enzyme with endo-xylanase activity.

Advisory Action at 12-13 and Final Office Action at 13-14 (emphasis in original). The Examiner concludes that the present claims are thus *prima facie* obvious in that "one of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that the product [was] not of innovation but of ordinary skill and common sense." Advisory Action at 13 and Final Office Action at 14 (emphasis and text in brackets in original).



**(i). The present invention is not a combination of prior art elements according to known methods which yield predictable results.**

The Examiner relies upon Haarasilta and Poutanen as the primary references in the present rejection. Haarasilta discloses the use of xylanases generally in baking products. However, Haarasilta does not teach or suggest the use of a bacterial xylanase as is presently claimed. Poutanen discusses that the use of xylanases generally increases viscosity, results in better "ovenspring," increases bread volume, and decreases staling in bread. *See, e.g.,* Poutanen at 303, right column and 304, bottom left column to right column. The only reference to dough stickiness in Poutanen may be found in Table 3, on page 304. The Table contains a list of effects disclosed for certain xylanases together with a reference to the document which discloses such effects. All of the xylanase examples found in Table 3 are xylanases extracted from fungal sources, *i.e., Aspergillus* and *Trichoderma*. The Table discloses that a specific fungal xylanase from *Aspergillus* caused an increase in the specific volume of wheat bread without causing stickiness:

A specific *Aspergillus awamori* endo-xylanase was effective in increasing the specific volume of wheat bread without causing stickiness.

Poutanen at 304. Poutanen is silent with regard to the effect a bacterial xylanase, as is presently claimed, may have on the stickiness of the dough.

At the time of the claimed invention, bacterial xylanases were known to produce very sticky doughs, as discussed in the specification at paragraphs [0010] - [0012] of U.S. Patent Application Publication No. 2004/0234998. Additionally, references such as Maat *et al.*, "Xylanases and their application in bakery," in XYLANS & XYLANASES ed. J. Visser *et al.* Elsevier:349-360 (1992) ("Maat") (cited by Poutanen and cited as document A27 in the IDS filed August 18, 2003) disclose that xylanases derived from fungal sources other than *Aspergillus awamori* and bacterial sources result in sticky dough:

We have identified a particular  $\beta$ -(1,4)-xylanase produced by an Aspergillus niger var awamori strain as being very effective in increasing the specific volume of breads, without giving rise to a negative side effect on dough handling (stickiness of the dough) *as can be observed with xylanases derived from other fungal or bacterial sources.*"

Maat at 349 (emphasis added).

The Examiner relies upon Paice or Wolf as allegedly describing a polynucleotide and polypeptide encoded by the polynucleotide having 100% sequence homology to the nucleotide sequence of SEQ ID NO:6 and the polypeptide of SEQ ID NO:5. Advisory Action at 4 and Final Office Action at 5. Paice relates to the isolation of a xylanase gene from *B. subtilis* and Wolf relates to the isolation of a xylanase gene from *B. subtilis* 168. Neither Paice nor Wolf disclose or suggest a bakery product or a dough for making a bakery product, let alone a bakery product or dough for making a bakery product, suitable for a foodstuff, comprising a polypeptide expressed from the nucleotide sequence of SEQ ID NO:6, as is presently claimed.

The Examiner also cites Campbell as allegedly describing a *Bacillus* xylanase enzyme having 100% sequence homology to the amino acid sequence of amino acid residues 29-213 of SEQ ID NO:5 (SEQ ID NO:37 of Campbell) and "also suggest[s] the use of said xylanase for altering the texture in bakery products (column 1)." Advisory Action at 4 and Final Office Action at 5. Campbell is directed to "a modified xylanase, which shows an improved thermostability when compared to the naturally occurring xylanase." Campbell at col. 1, ll. 7-9. Campbell is further directed to "a modified xylanase, wherein said xylanase has increased thermostability and wherein said xylanase is modified through either the introduction of a non-native disulfide bridge, introduction of an N-terminal mutation, or both." Campbell at col. 1, ll. 10-14. As such, Campbell is directed to modified xylanases, in particular modified xylanases of *B. circulans*, for use in the pulp manufacturing industry. See Campbell at Abstract. Campbell further mentions that thermotolerant variants of xylanases can also be used in the food processing industry. *Id.*

Campbell makes reference to a bakery use for xylanases in general, in the background section which lists uses in "non-pulp applications":

Xylanase also has uses in non-pulp applications. Xylanases have been reported to be useful in clarifying juice and wine (Zeikus. J. G., Lee, Y.-E., and Saha, B. C. 1991. ACS Symp. Ser. 460:36-51; Beily, P. 1991. ACS Symp. Ser. 460:408-416; Woodward J. 1984. Top Enzyme Ferment. Biotechnol. 8:9-30), extracting coffee, plant oils and starch (McCleary, B. V. 1986. Int. J. Biol. Macromol. 8:349-354; Beily, P. 1991. ACS Symp. Ser. 460:408-416; Woodward J. 1984. Top Enzyme Ferment. Biotechnol. 8:9-30), for the production of food thickeners (Zeikus. J. G., Lee, Y.-E., and Saha, B. C. 1991. ACS Symp. Ser. 460:36-51), **altering texture in bakery products (Maat, J., Roza, M., Verbakel, J., Stam, H., Santos da Silva, M. J., Bosse, M., Egmond, M. R., Hagemans, M. L. D., v. Gorcom, R. F. M., Hessing, J. G. M., v.d. Hodel, C.A.M.J.J., and Rotterdam, C. 1992. In Xylans and xylanases. Visser, J., Beldman, G., Kusters-van Someren, M. A. and Voragen, A. G. J., eds. Elsevier Sci pub., Amsterdam. ISBN 0-444-894-772; McCleary, B. V. 1986. Int. J. Biol. Macromol. 8:349-354)**, and in the washing of super precision devices and semiconductors (Takayuki, I., Shoji, S. U.S. Pat. No. 5,078,802, issue date 92 Jan. 07). **Several of these application [sic] could benefit from a thermostable xylanase**, for example, food processing at elevated temperatures.

Campbell at col. 1, ll. 43-68 (emphasis added). Campbell cites Maat which teaches a fungal xylanase and, as explained *infra*, teaches away from the use of a bacterial xylanase in dough. Thus, Campbell teaches modified xylanases based on naturally occurring xylanases with a vague reference to their use in food processing. Thus, Appellants maintain that neither Paice, Wolf, nor Campbell teach or suggest that the claimed bacterial xylanase would have particular use in baking applications or doughs.

Appellants emphasize that one of skill in the art would not have been able to predict the effects on dough stickiness of a bacterial xylanase which is expressed from the nucleotide sequence of SEQ ID NO:6. Indeed, one of skill in the art would have predicted that a bacterial xylanase would have a *negative* impact on dough stickiness based on the teaching of Maat, for

example. Furthermore, it was unexpected, and thus unpredictable, that the xylanase expressed from the nucleotide sequence of SEQ ID NO:6 would have resulted in decreased dough stickiness compared to other bacterial and fungal xylanases, as discussed further *infra*. None of the references teach or suggest that bacterial xylanases, and in particular the bacterial xylanase expressed from the nucleotide sequence of SEQ ID NO:6, would be effective in decreasing dough stickiness.

Thus, the present invention is not a combination of prior art elements according to known methods which yield predictable results or a simple substitution of one known element for another to obtain predictable results. One of skill in the art would not have predicted that a bacterial xylanase would be effective in decreasing dough stickiness.

**(ii). Claimed invention is not "obvious to try."**

Appellants also emphasize that the present invention cannot be considered "obvious to try" as a finite number of identified, predictable solutions did not exist. Furthermore, based on the unpredictability in the art described *supra*, one of skill in the art would not have had a reasonable expectation of success.

Indeed, there were a vast number of xylanases, from many different organisms, known at the time of the invention. A quick search of the NCBI protein database ([www.ncbi.nlm.nih.gov/sites/entrez](http://www.ncbi.nlm.nih.gov/sites/entrez)) for "xylanase" sequences published between January 1, 1980 and January 1, 1999 resulted in 494 sequences. One of skill in the art could have chosen any one of these xylanases. Furthermore, as discussed, *supra*, one of skill in the art would have had no reasonable expectation of success that bacterial xylanases would have improved certain qualities of dough or bakery products without the negative side-effect of dough stickiness.

The Examiner has provided no motivation as to why one of skill in the art would have used the specifically claimed bacterial xylanase obtained by expressing the polynucleotide sequence of SEQ ID NO:6 or the xylanase having amino acids 29-213 of SEQ ID NO:5 over all other xylanases which were known in the art, specifically since it was known in the art that

bacterial xylanases were known to produce very sticky doughs. Specification at ¶¶ [0010] - [0012] and Maat.

This broad selection of xylanases, with no reasonable expectation of success, cannot form the basis for a finite number of "identified and predictable solutions" as required by the *KSR* and *Takeda Chemical Industries, Ltd. V. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (stating that "the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation."). The court emphasized that obviousness requires that the prior art give a reason or motivation to make the specific composition claimed. *Id.* at 1356. No art has been cited which would have narrowed the choices of a xylanase for a dough with decreased stickiness. *Takeda*, 492 F.3d 1360 (invention was non-obvious as there was nothing in the prior art to narrow the possibilities of a lead compound to modify.). Here, where the record reveals no such reason for selecting the xylanase produced by the polynucleotide of SEQ ID NO:6, the obviousness rejection is improper, and should be reversed.

**(iii). No motivation to select the bacterial xylanase produced by the polynucleotide of SEQ ID NO:6 without the use of impermissible hindsight.**

The Examiner maintains that there would have been motivation to select the bacterial xylanases of Paice, Wolf or Campbell as one of skill in the art would have been interested in understanding the effect of the cited xylanases in a bakery product or dough:

[T]hus a skilled artisan would certainly be interested to understand the effect of the xylanase isolated by Paice et al., or Wolf et al., or Campbell et al., on a bakery product or a dough, i.e. its mechanism of action and would be motivated to employ the xylanase isolated by Paice et al., or Wolf et al., and Campbell et al.

Advisory Action at 10 and Final Office Action at 11. However, the Examiner has failed to provide a motivation as to why one of skill in the art would have chosen the particular bacterial xylanase of Paice, Wolf or Campbell over all other xylanases known at the time of the invention.

Relying upon impermissible hindsight, the Examiner has arrived at the xylanases disclosed in Paice, Wolf and Campbell based on sequence comparison from Appellants' disclosure. *See KSR* at 17 ("A factfinder should be aware...of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."); *see also* MPEP § 2142.

Here, at the time of the invention, a large number of xylanases were known, any of which could have been selected by one of skill in the art. The Examiner has not provided any reason why out of the numerous known xylanases at the time of the invention, one of skill in the art would have chosen the bacterial xylanase produced by the polynucleotide of SEQ ID NO:6. Additionally, neither Paice, Wolf nor Campbell teach or suggest that the claimed xylanase would have use in particular baking applications. The Examiner has arrived at the xylanases disclosed in Paice, Wolf and Campbell based solely on hindsight sequence comparison from Appellants' disclosure.

Appellants maintain that the Examiner relies upon impermissible hindsight to create his rejection. Thus, the present invention cannot be obvious.

Therefore under *Graham* and *KSR*, the Examiner has failed to establish a *prima facie* case of obviousness as one of skill in the art would neither have predicted, nor had a reasonable expectation of success, that a bacterial xylanase would be effective in decreasing dough stickiness. Furthermore, a finite number of identified, predictable solutions did not exist as it would not have been obvious to select the bacterial xylanase encoded by the polynucleotide sequence of SEQ ID NO:6 from the vast array of known xylanase protein sequences. The Examiner relies solely upon impermissible hindsight to combine the cited references. Appellants maintain that the invention is, therefore, not rendered obvious in view of the cited art.

**B. Appellants' Claimed Invention Demonstrates Unexpected Results.**

The claimed invention demonstrates unexpected results which are indicia of nonobviousness and must be considered by the Examiner. MPEP § 716.01(a). The Examiner

has failed to comment regarding Appellants' discovery that the xylanase produced by the polynucleotide sequence of SEQ ID NO:6 had a surprising and unexpected effect. In particular, the claimed xylanase produced a significantly less sticky dough as compared with other xylanases, including other bacterial xylanases. *See* Example 1.

In Example 1 of the present application, two fungal xylanases (X1 and Nova) are compared with the bacterial xylanase obtained by expression of the nucleotide sequence of SEQ ID NO:6 (referred to as BX in the captioned application). *See e.g.* Tables 1 and 2 of the specification. Use of the bacterial BX xylanase resulted in dough that was less sticky than other fungal xylanases. Additionally, Example 1 of the specification compares the Röhm bacterial xylanase (which differs from the xylanase of the present invention by only a small number of amino acids) with the bacterial BX xylanase obtained by expression of the nucleotide sequence of SEQ ID NO:6. *See e.g.* Tables 3 and 4 of the specification. The results in the captioned application demonstrate that BX gave rise to a less sticky dough compared with the Röhm bacterial xylanase.

As discussed previously, at the time of the claimed invention, bacterial xylanases were known to produce very sticky doughs. Specification at ¶¶ [0010] - [0012] and Maat. Thus, it was unexpected that the use of the bacterial xylanase (BX) resulted in dough which was less sticky than other fungal xylanases. Furthermore, it was unexpected that another bacterial xylanase (Röhm), with a similar amino acid sequence, would not have the same effect.

These results also show that there was a high level of unpredictability in the art with regard to which xylanases would yield less sticky dough. Indeed, the fungal and bacterial xylanases had different effects on the stickiness of the dough produced in the specification. *See e.g.* Table 2 of the specification. Additionally, this data also shows that there are differences in the stickiness of dough produced by different bacterial xylanases. *See* Table 4.

Thus, Appellants maintain that a dough created with a bacterial xylanase which was less sticky than a dough made with a fungal xylanase was unexpected and is evidence of the non-obviousness of the present invention.

**C. The Cited Art Teaches Away from the Claimed Invention.**

The Examiner relies on Poutanen, discussed *supra*, as a primary reference in the present rejection. As discussed previously, the only reference to dough stickiness in Poutanen may be found in Table 3, on page 304. Table 3 discloses that a specific fungal xylanase from *Aspergillus* caused an increase in the specific volume of wheat bread without causing stickiness citing Maat, also discussed *supra*:

A specific *Aspergillus awamori* endo-xylanase was effective in increasing the specific volume of wheat bread without causing stickiness. Maat et al. (1991).

Poutanen at 304.

Appellants maintain that the Poutanen and Maat references teach *away* from the use of bacterial xylanases in bakery products or doughs for bakery products, as required by the claimed invention. Specifically Maat states that the use of *Aspergillus awamori* (fungal) xylanase is effective in "increasing the specific volume of breads, without giving rise to a negative side effect on dough handling (stickiness of the dough) *as can be observed with xylanases derived from other fungal or bacterial sources.*" Maat at 349 (emphasis added).

The Examiner has maintained that he does not have to consider the disclosure in Maat as the reference was never cited by the Examiner and that the argument is not relevant to the Examiner's rejection:

[The] examiner would like to state that said reference was never cited by the Examiner in the rejection and the applicants use of the reference in the argument is not relevant to the basis of [the] rejection adopted by the examiner.



Advisory Action at 9 and Final Office Action at 10-11 (text in brackets added). The Examiner further stated that the reference was not relevant as the Examiner had already provided the reason for the use of a xylanase isolated by Paice, Wolf, Campbell and Haarasilta:

[The] examiner has provided the reason for the use of xylanases isolated by Paice et al., Wolf et al., Campbell et al., and Haarasilta et al. that teach the structural and functional elements of the instant invention and having the desired activity.

Advisory Action at 9 and Office Action at 11.

However, Appellants maintain that the Examiner must consider Maat as 1) the Examiner must consider the Poutanen reference as a whole; 2) Maat was cited in Table 3 by Poutanen for the very proposition the Examiner is relying upon in his rejection (*i.e.* "the addition of xylanase was effective in increasing the specific volume of wheat bread without causing stickiness (Table 3, page 304)" (Advisory Action at 3); and 3) the standard for an obviousness analysis is one of ordinary skill in the art, not the Examiner's perspective.

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made.

MPEP § 2142. An obviousness analysis requires what one of skill in the art would have understood the reference to teach. 35 U.S.C. § 103 ("A patent may not be obtained...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.") (emphasis added).

Thus, Appellants maintain that one of ordinary skill in the art reviewing Poutanen would have considered that only the specific *Aspergillus* fungal xylanase cited in Table 3 of Poutanen, and relied upon by the Examiner in his rejection, was effective at increasing the specific volume of wheat bread without causing stickiness. On considering whether the teaching of Poutanen could be applied to other xylanases, a person of ordinary skill in the art would have sought out

further information in the form of the reference cited by Poutanen, *i.e.*, Maat. Maat discloses that the specific funga enzyme discussed in Poutanen is very effective at increasing specific volumes of breads without giving rise to dough stickiness as is observed with other xylanases derived from other fungal or bacterial sources:

We have identified a particular  $\beta$ -(1,4)-xylanase produced by an Aspergillus niger var. awamori strain as being very effective in increasing specific volume of breads, without giving rise to a negative side effect on dough handling (stickiness of the dough) *as can be observed with xylanases derived from other fungal or bacterial sources*.

Maat at 349 (emphasis added).

The Examiner must rely upon the teaching of the cited art as a whole and how it would be interpreted by one of skill in the art. Maat is being cited by Appellants in order to rebut the Examiner's interpretation of Poutanen and provide support for Appellants' assertion that Poutanen teaches away from the use of bacterial xylanases. In view of the above, and because Maat is cited in Poutanen for the exact proposition the Examiner is relying upon in his rejection (*i.e.*, xylanases improve the stickiness of dough), the Examiner cannot just choose to ignore Maat.

Thus, Appellants maintain that the cited art teaches away from the use of bacterial xylanases as is presently claimed for decreasing dough stickiness.

**2. Claim 67 is not obvious over Haarasilta or Poutanen, Paice or Wolf and Campbell and further in view of Autio.**

The Examiner also rejected claim 67 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Haarasilta or Poutanen, Paice or Wolf and Campbell and further in view of Autio. Advisory Action at 5 and Final Office Action at 6. The Examiner states that the combination of Haarasilta or Poutanen, Paice or Wolf and Campbell do not specifically teach xylanase free of glucanase enzymes. *Id.* However, the Examiner alleges that Autio teaches "the effects of purified xylanase and glucanase on the structural and baking characteristics of doughs,

said reference discloses that the addition of glucanase had a hardening effect on doughs and bakery products." Advisory Action at 5-6 and Final Office Action at 6-7. The Examiner alleges that it would have been obvious to combine the teachings of Haarasilta or Poutanen, Paice or Wolf, Campbell and Autio to produce the baking products and doughs with xylanase devoid of glucanase as the "presence of glucanases catalyzes the breakdown of substrates that results in unwanted hardening effect on said products." Advisory Action at 6 and Final Office Action at 7 .

For the reasons discussed above, Autio does not cure the deficiencies of Haarasilta Poutanen, Paice, Wolf and Campbell. Additionally, Autio relates to the use of a purified fungus (*Trichoderma reesei*) xylanase in rye doughs and the effects thereof. See Autio, Materials & Methods at 19. Autio does not disclose the use of a bacterial xylanase in dough, let alone a bacterial xylanase expressed from the nucleotide sequence of SEQ ID NO:6. In addition, Autio does not teach or suggest that the use of such a bacterial enzyme will give rise to a less sticky dough compared with an otherwise identical dough prepared by incorporating a fungal xylanase instead of a bacterial xylanase.

### **3. Conclusion**

In view of the foregoing discussion, Appellants submit that the subject matter of claims 56-67 and 69-70 are not obvious over the cited references. The Examiner has failed to establish a *prima facie* case of obviousness, particularly without relying upon impermissible hindsight. Additionally, the cited art teaches away from the claimed invention and Appellants have provided evidence of non-obviousness in the form of unexpected results.

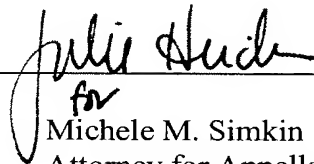
Accordingly, Appellants respectfully request that the Board reverse the Examiner's obviousness rejection and remand this application for issue.

Respectfully submitted,

Date May 27, 2009

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

By

  
for

Michele M. Simkin  
Attorney for Appellants  
Registration No. 34,717

Reg # 54,161

**VIII. CLAIMS APPENDIX**

56. A bakery product or a dough for making a bakery product comprising a polypeptide expressed from the nucleotide sequence of SEQ ID NO:6, wherein said bakery product or dough for making a bakery product is suitable for use in a foodstuff.
57. The bakery product or dough for making a bakery product of claim 56, wherein said polypeptide does not contain a leader sequence.
58. The bakery product or dough for making a bakery product of claim 56, wherein said polypeptide has the amino acid sequence of SEQ ID NO:5.
59. The bakery product or dough for making a bakery product of claim 57, wherein said polypeptide has the amino acid sequence of amino acids 29-213 of SEQ ID NO:5.
60. A dough for making a bakery product prepared by incorporating a bacterial xylanase comprising a polypeptide expressed from the nucleotide sequence of SEQ ID NO:6, whereby the resultant dough is less sticky than an otherwise identical dough prepared by incorporating a fungal xylanase instead of said bacterial xylanase.
61. The dough of claim 60, wherein said polypeptide does not contain a leader sequence.
62. The dough of claim 60, wherein said polypeptide has the amino acid sequence of SEQ ID NO:5.
63. The dough of claim 62, wherein said polypeptide has the amino acid sequence of amino acids 29-213 of SEQ ID NO:5.

64. A bakery product prepared by baking the dough of claim 60.
65. The dough of claim 60, comprising wheat flour, water and a bacterial xylanase expressed from the nucleotide sequence of SEQ ID NO:6.
66. The dough of claim 65, wherein said bacterial xylanase is from a *Bacillus subtilis* strain.
67. The dough of claim 65, wherein said bacterial xylanase is free of detrimental levels of glucanase enzymes.
69. The dough of claim 65, further comprising yeast.
70. A bakery product prepared by baking the dough of claim 69.

**IX. EVIDENCE APPENDIX**

1. Maat *et al.*, "Xylanases and their application in bakery," in *XYLANS & XYLANASES* ed. J. Visser *et al.* Elsevier: 349-360 (1992), cited by Appellants as document **A27** in the IDS filed August 18, 2003 and considered by the Examiner May 11, 2006.

**X. RELATED PROCEEDINGS APPENDIX**

None